



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0519]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry on How to Submit Information in Electronic Format to the Center for Veterinary Medicine Using the Food and Drug Administration Electronic Submission Gateway

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or emailed to oir_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0454. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, Three White Flint North, 10A63, 11601 Landsdown St., North Bethesda, MD 20852, PRASStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Guidance for Industry on How to Submit Information in Electronic Format to the Center for Veterinary Medicine Using the Food and Drug Administration Electronic Submission Gateway--

21 CFR 11.2

OMB Control Number 0910-0454--Extension

We accept certain types of submissions electronically with no requirement for a paper copy. These types of documents are listed in public docket 97S-0251 as required by 21 CFR 11.2. Our ability to receive and process information submitted electronically is limited by our current information technology capabilities and the requirements of the Electronic Records; Electronic Signatures final regulation. Our guidance entitled "Guidance for Industry #108: How to Submit Information in Electronic Format to CVM Using the FDA Electronic Submission Gateway" outlines general standards to be used for the submission of any electronic information to CVM using the FDA Electronic Submission Gateway (ESG). The likely respondents are sponsors for new animal drug applications.

In the Federal Register of April 8, 2016 (81 FR 20647), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received one comment; however, it did not pertain to the information collection.

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden¹

21 CFR Section	FDA Form No.	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
11.2	3538	29	1.3	38	.08 (5 minutes)	3.0

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

We base our estimates on our experience with the submission of electronic information to us using the FDA ESG and the number of electronic registration or change requests received between January 1, 2014, and December 31, 2014.

Dated: September 26, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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